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08/04/23 • BIG PHARMA › NEWS

Despite 12 Deaths During Clinical Trials, CDC Signs Off on RSV Shots for Newborns

Medical experts criticized the Centers for Disease Control and Prevention's Thursday decision to recommend a "new immunization" for newborns to protect against respiratory syncytial virus, or RSV, calling the move unnecessary and not worth the known risks.

By Michael Nevradakis, Ph.D.

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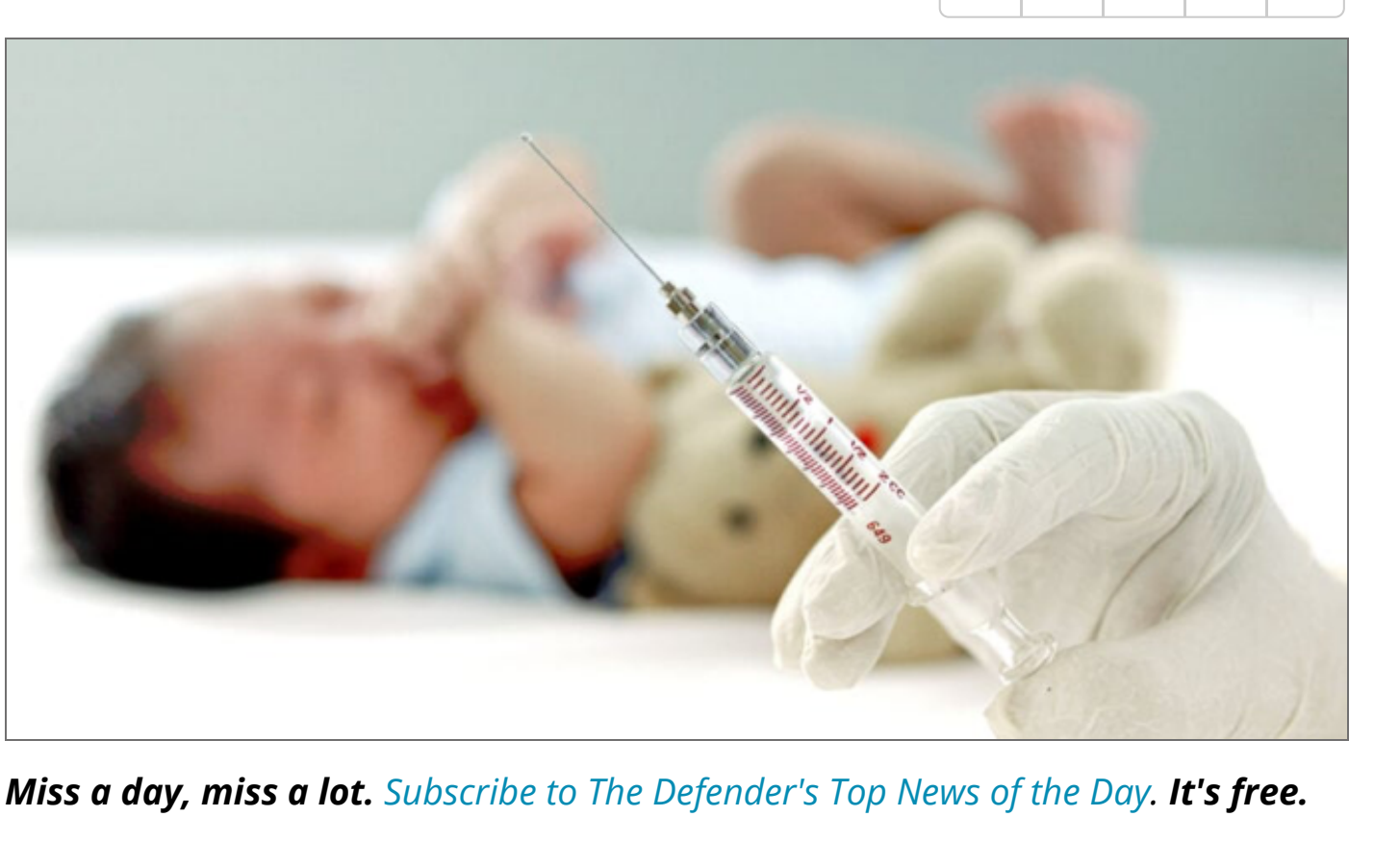

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The Centers for Disease Control and Prevention (CDC) on Thursday recommended the first-ever monoclonal antibody marketed as a defense for all newborns against respiratory syncytial virus, or RSV.

Beyfortus, also known as nirsevimab, is produced by pharma giants Sanofi and AstraZeneca.

In a press release, the CDC referred to the drug as a "powerful tool" and a "new immunization." According to the agency:

> "ACIP [Advisory Committee on Immunization Practices] voted to include nirsevimab in the Vaccines for Children program, which provides recommended vaccines and immunizations at no cost to about half of the nation's children.
>
> "CDC is currently working to make nirsevimab available through the Vaccines for Children program. Healthcare providers will be a key partner in CDC's outreach efforts. Additional clinical guidance and healthcare provider education material will be provided by CDC in the coming months."

According to The Associated Press (AP), the drug will be offered as a "one-time shot for infants born just before or during the RSV season and for those less than 8 months old before the season starts," and for some high-risk 8-19-month-old infants.

Infants in the high-risk group include "immunocompromised children and those with chronic lung disease — as well as Native American and Alaska Native children, who have RSV hospitalization rates between four and 10 times that of the general population," STAT News reported.

CDC's ACIP approved the recommendations in a unanimous 10-0 vote. Although not bound by ACIP's vote, CDC Director Mandy Cohen signed off on the recommendations later on Thursday, according to CNBC.

Beyfortus will be "broadly available for all infants regardless of whether they have a health condition," CNBC reported, adding that it will be "administered as a single dose."

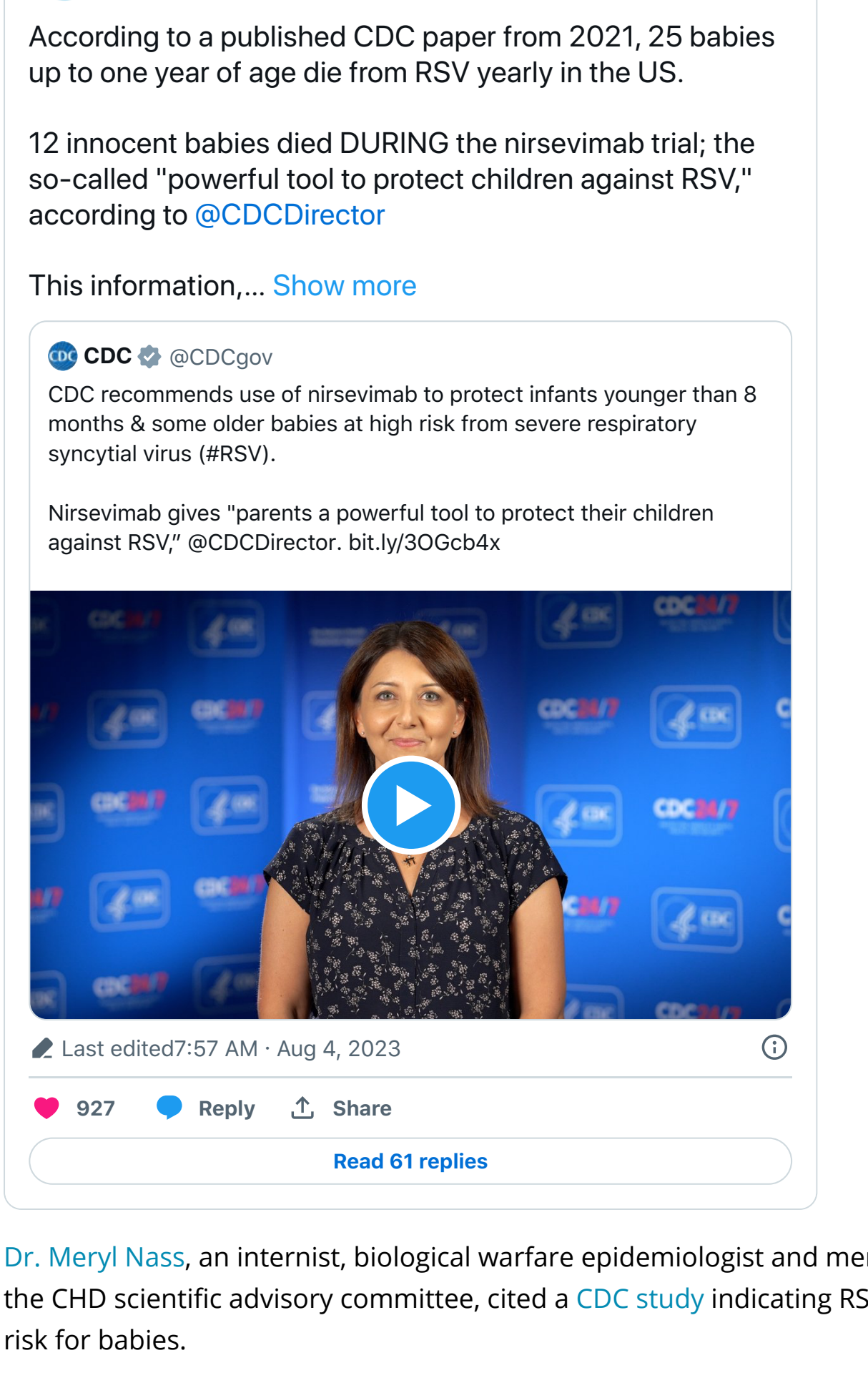
Some medical experts criticized the recommendation, pointing to infant deaths that occurred during the clinical trial for Beyfortus and questioning the need for their widespread administration to this age group.

Cardiologist Dr. Peter McCullough told The Defender:

> "While monoclonal antibodies are reasonably safe and effective, they are not clinically indicated nor medically necessary in all newborns.
>
> "This new preventive strategy should be considered in rare cases with baseline lung disease such as severe asthma or cystic fibrosis. Injecting all newborns should be off the table and rejected by parents who want to avoid unnecessary drugs and potential harms."

Brian Hooker, Ph.D., P.E., senior director of science and research for Children's Health Defense (CHD), cited the significant number of infant deaths during Beyfortus' clinical trial in his remarks:

> "This is really too bad and seems to be a part of the Department of Health and Human Services' scare tactics recently regarding RSV, which is generally a mild infection that finds its origin during the development of the polio vaccine.
>
> "The efficacy of the antibodies from clinical trials is woefully low and the circulating half-life of such a therapeutic may be as low as two weeks.
>
> "I'm also worried about allergic reactions in newborns, especially given the high dose of antibodies and especially given that 12 infants died in the experimental arm of the clinical trial."



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According to a published CDC paper from 2021, 25 babies up to one year of age die from RSV yearly in the US.

12 innocent babies died DURING the nirsevimab trial; the so-called "powerful tool to protect children against RSV," according to @CDCDirector

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CDC @CDCgov

CDC recommends use of nirsevimab to protect infants younger than 8 months & some older babies at high risk from severe respiratory syncytial virus (#RSV).

Nirsevimab gives "parents a powerful tool to protect their children against RSV," @CDCDirector. bit.ly/3OGcb4x

Last edited7:57 AM · Aug 4, 2023

Dr. Meryl Nass, an internist, biological warfare epidemiologist and member of the CHD scientific advisory committee, cited a CDC study indicating RSV's low risk for babies.

She also cited the lack of demonstrated long-term efficacy for such monoclonal antibodies, writing on her Substack:

> "There is already resistance in RSV strains to this product, and so as it gets used, the resistant strains will outperform the susceptible ones, and the RSV ecology is likely to change … meaning its use will likely not last very long."

ACIP recommended adding Beyfortus to the childhood vaccine schedule, which would provide manufacturers a waiver of liability, but also recommended coding it as a drug for insurance purposes and leaving it out of the National Vaccine Injury Compensation Program (NVICP).

ACIP ignores 'unrelated' infant deaths during Beyfortus clinical trial

ACIP member and CDC epidemiologist Jefferson Jones, M.D., MPH, said during Thursday's meeting, "The work group felt that RSV-associated disease in infants born, during, or entering their first RSV season is of public health importance."

Also during Thursday's meeting, clinical data regarding the effectiveness of Beyfortus was presented, indicating that it was "up to 75% effective at preventing lower respiratory tract infections that required medical attention among infants and 78% effective at preventing hospitalization," CNBC reported.

However, Jones acknowledged that "a primary limitation" in the clinical trial was that "RSV testing may be more common for children with risk conditions inflating RSV-specific hospitalization rates."

"Overall, the evidence rating was very low certainty, and this was downgraded because of indirectness, because of the use of pharmacokinetic data as a surrogate for efficacy," he added. "The population did not include children that match the proposed indication outside of chronic lung disease, congenital heart disease … the study was small in size and … no placebo group was included for a comparison."

Several infant deaths — 12 in all — were reported during the clinical trial, which the U.S. Food and Drug Administration (FDA) claimed during a June review were "unrelated" to the antibody. On Thursday, Jones repeated this claim during the ACIP meeting, stating that "no RSV-associated deaths were recorded."

CNBC reported in June that of the 12 infants, "Four died from cardiac disease, two died from gastroenteritis, two died from unknown causes but were likely cases [of] sudden infant death syndrome, one died from a tumor, one died from COVID, one died from a skull fracture, and one died of pneumonia."

And STAT News reported in June that no data are available "about whether giving nirsevimab to a baby whose mother was vaccinated against RSV during pregnancy would give the infant more protection or would be a waste of the product."

During Thursday's meeting, Jones said, "The most commonly reported adverse reaction were injection site reactions at 0.3% and rash at 0.9%."

And, further justifying the committee's subsequent unanimous vote, Jones cited data from an August 2022 University of Iowa and Rand Corporation study, stating that "70% of respondents said they definitely or probably would get an RSV antibody injection for their baby if safe and effective."

However, Jones also stated that "only 33% of respondents thought their baby definitely or probably would get an RSV infection within one year after being born," according to data from the same study.

Nevertheless, Jones said at Thursday's meeting, "The work group determined that the target population probably feels that the desirable effects are large relative to undesirable effects."

Jones did acknowledge, however, that "the work group felt that the desirable consequences probably outweigh the undesirable consequences in most settings with a minority opinion that desirable consequences clearly outweigh the undesirable consequences," indicating at least a small amount of uncertainty among its members.

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Beyfortus label ignores adverse events, 'hardly worth the paper it is printed on'

Nass also took issue with ACIP members downplaying the potential risks of Beyfortus and noted that Beyfortus' product label does not specify most potential adverse events associated with the drug.

"According to the label, the only risks specified are rashes and anaphylaxis. This is a very uninformative label. Hardly worth the paper it is printed on," Nass wrote.

The label does not provide any details about side effects," Nass added, noting that "It can be difficult to tell in a newborn. And the manufacturer and FDA appear to use that as a benefit, requiring less safety evaluation."

"The label does not inform us of the causes of deaths," Nass said, referring to the 12 infant deaths which occurred during the clinical trial for Beyfortus. "This is extremely worrisome."

The label also states, in part, that "Carcinogenesis, mutagenesis and reproductive toxicity studies have not been performed with Beyfortus" and that "No formal drug interaction studies have been performed" with the drug. There is also "limited experience with co-administration of Beyfortus with vaccines."

Nass also noted that there are risks associated with the administration of monoclonal antibodies more broadly, citing the Cleveland Clinic, which states that "Infusion reactions are common, and occur during or shortly after monoclonal antibody treatment."

There are also "more serious but less common risks linked to unwanted immune system reactions, such as acute anaphylaxis, cytokine release syndrome (CRS) and serum sickness."

"Some monoclonal antibodies have been associated with allergic reactions and skin rashes," CNBC reported.

Nass rhetorically questioned whether any monoclonal antibody has ever been administered on a wide scale to children and if any such drugs have ever been approved for newborns, writing that the answer is "no" in each instance.

Perhaps partially acknowledging such concerns, STAT News reported that "experts cautioned that rolling the drug out across the country would be difficult. The U.S. has never before tried to give this type of medicine to nearly every infant."

STAT News quoted ACIP member Dr. Helen Keipp Talbot, a Vanderbilt University infectious disease specialist, who said Beyfortus "is life-changing" and that she's "very excited" about it, but that she "just hope[s] we can get through the hurdles."

CDC 'playing fast and loose with the definition of vaccine'

Experts are also raising questions about the CDC's treatment of Beyfortus as a vaccine in some instances and as a drug in other cases.

According to the AP, "the expert panel also supported including it in Vaccines for Children (VFC), a government program providing free immunizations. The American Academy of Pediatrics is urging hospitals to stock Beyfortus so that newborns can get it during RSV season before they go home."

STAT News reported that Vaccines for Children is a "30-year-old program that assures children of parents without health insurance can be vaccinated for free."

According to CNBC, "Beyfortus works like a vaccine, but the shot is considered a drug, not a vaccine, because it is an antibody injection. Vaccines prepare the body's immune system to release antibodies that fight viruses, while Beyfortus injects these antibodies directly into the bloodstream."

Nass took issue with this juggling of classifications, writing on her Substack:

> "CDC is playing fast and loose with the definition of vaccine again, calling it a vaccine when convenient and a drug when that is more convenient. In order to get it onto the childhood vaccine schedule it becomes a vaccine — giving the manufacturer a waiver of liability. But it must be coded for reimbursement as a drug.
>
> "It will be covered by the Affordable Care Act insurance program as a vaccine. But if there is an adverse event when it is used alone, the adverse event report will be filed in the (FAERS) [FDA Adverse Event Reporting System] belonging to FDA. If it is administered along with vaccines, the adverse event report will be sent to VAERS [Vaccine Adverse Event Reporting System], belonging jointly to FDA and CDC."

In justifying Beyfortus' mixed classification as either a vaccine or drug, Dr. Georgina Peacock, director of the Immunization Services Division at the CDC's National Center for Immunization and Respiratory Diseases, said at Thursday's meeting:

> "When we look at the Vaccines for Children program then there is no statutory definition of vaccine in the statute when we look at the Affordable Care Act. Similarly, there is no statutory definition of vaccine in the Affordable Care Act.
>
> "So, CDC has determined that [Beyfortus] is eligible for inclusion in the childhood immunization schedule and the Vaccines for Children program."

She added that "this product … does look similar to other routine vaccines. It's administered intramuscularly with a single-dose prefilled syringe. It can be administered simultaneously with other childhood vaccines … the storage and handling is similar to other routine vaccines."

George Reed Grimes, M.D., MPH, director of the Division of Injury Compensation Programs at the Health Resources and Services Administration's Health Systems Bureau, said "the Vaccine for Children Program and the National Vaccine Injury Compensation Program are separate. So just inclusion in the VFC would not trigger inclusion in the NVICP or vice versa."

The NVICP covers injuries related to vaccines that are routinely administered to children and pregnant women.

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Is widespread administration of an RSV monoclonal antibody to infants needed?

According to the AP, "In the U.S., about 58,000 children younger than 5 are hospitalized for RSV each year and several hundred die," while according to CNBC, "RSV is the leading cause of hospitalization among infants in the U.S."

CNBC previously reported that the U.S. "suffered an unusually severe RSV season" last winter. The New York Times reported on a "tripledemic" involving RSV, flu and COVID-19, "that swamped children's hospitals and some I.C.U. wards."

According to the CDC, nearly all children are infected with RSV before the age of 2.

However, according to Nass, the risk of death from RSV is lower than the risk of injury or death by vaccines and other treatments being pushed for the illness.

In May, Nass wrote that the CDC published a paper on RSV deaths in infants between 2009 and 2019, which found "were only a total of 300 deaths in children less than one year over the 12 years, or 25 on average per year."

Nass added at the time that the number of injuries that may be caused by vaccines or other treatments during pregnancy "is almost certainly going to outweigh the loss of 25 babies a year from RSV."

Citing CDC figures, Nass wrote on her Substack yesterday that "4 million babies are born yearly in the U.S. 20,000 die in their first year. RSV kills 0.125% of them. It way down the list of top causes of death." She added:

> "RSV almost never causes chronic problems, except perhaps asthma. Or maybe children with an asthma tendency are also more susceptible to severe RSV.
>
> "RSV does hospitalize a lot of U.S. infants. It frightens parents and causes a lot of work for doctors. And so, this group of pediatricians on CDC's advisory committee went gaga over this new product, which is supposed to be 70-80% effective at preventing severe RSV disease."

More RSV drugs in the pipeline

According to the AP, Beyfortus "is expected to be ready in the fall before the RSV season, typically November through March." Its expected cost is $495 per dose, which will be "covered by insurance," although "[ACIP] Panelists acknowledged that it will be a challenge at first to give the shot and for providers to be reimbursed by insurers."

CNBC reported that "It could potentially take months for some insurance plans to update their policies to comply with the requirement."

For high-risk children in the 8-to-19-month group, "the drug will cost twice as much," STAT News reported, because they will receive a second injection.

According to Endpoints News, Beyfortus has already received regulatory approval in the European Union, United Kingdom and Canada, but "it has not yet launched in any of those markets."

The approval of Beyfortus comes as a range of RSV vaccines have recently been approved or are in the pipeline for approval.

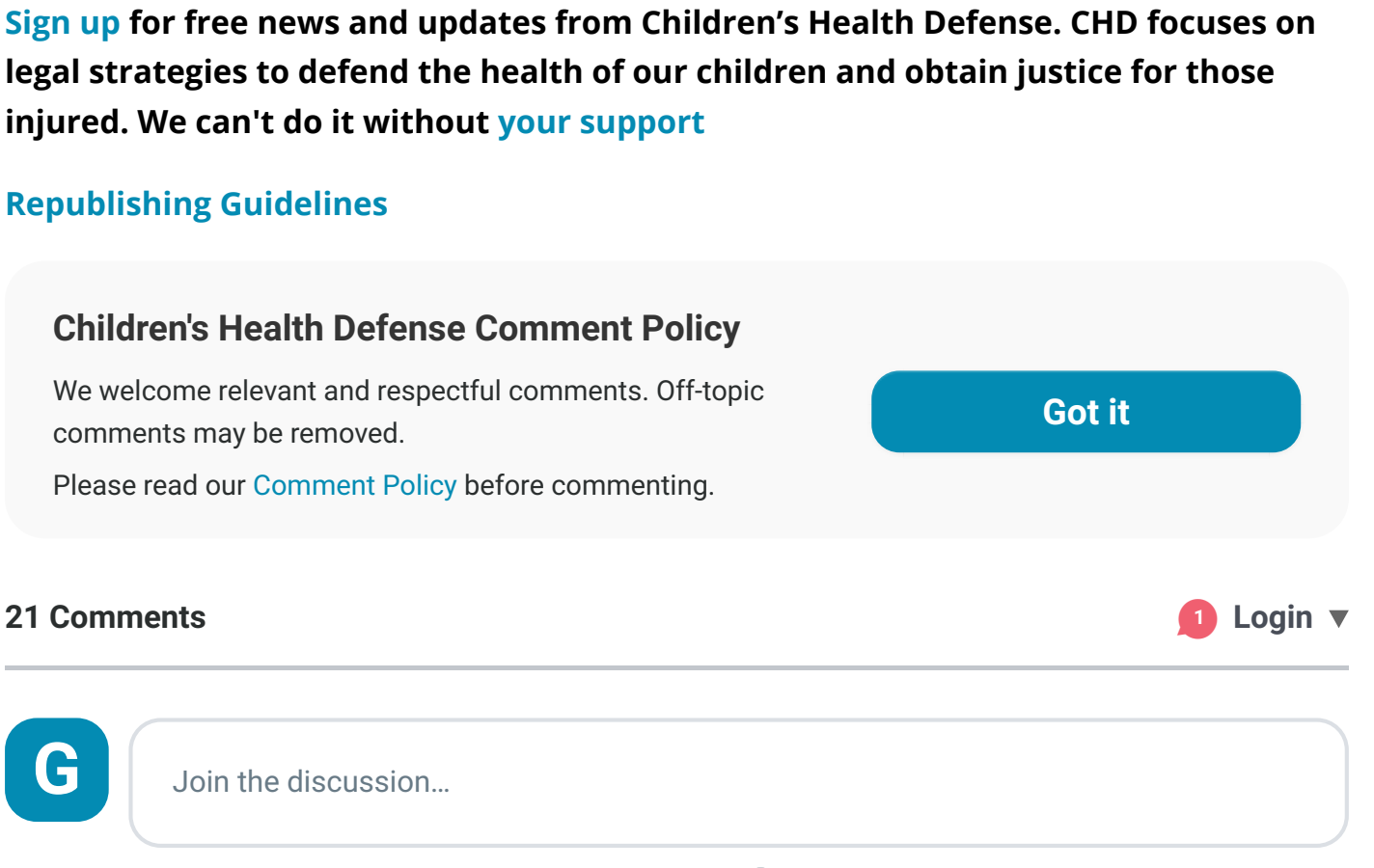
In May, the FDA approved Pfizer's Abrysvo for administration to pregnant women, despite concerns raised by some medical experts about premature births identified during clinical trials. FDA approval is expected later this month, according to the AP.

And also in May, the FDA approved Arexvy, an RSV vaccine developed by GlaxoSmithKline Biologicals (GSK), and Pfizer's Abrysvo, for people ages 60 and older. In June, the ACIP recommended the two vaccines, and later that month, outgoing CDC Director Rochelle Walensky approved the recommendation.

Abrysvo has been linked to Guillain-Barré syndrome, a rare disorder in which the body's immune system attacks its own nerves. Symptoms can range from brief weakness to paralysis.

Another monoclonal antibody for the treatment of RSV, palivizumab, is available on the market, but according to CNBC, it "is primarily used for pre-term babies and those with congenital heart and lung conditions" and "is also more difficult to administer because infants have to receive a shot monthly during RSV season."

Watch the ACIP meeting here:



ACIP MEETING
RSV VACCINES + MONOCLONAL ANTIBODIES
August 3, 2023 at 11am - 3:30 ET
Liveblog by Meryl Nass, M.D.
WATCH ON CHD.TV
CDC

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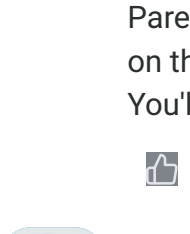

Michael Nevradakis, Ph.D.

Michael Nevradakis, Ph.D., based in Athens, Greece, is a senior reporter for The Defender and part of the rotation of hosts for CHD.TV's "Good Morning CHD."

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Best Newest Oldest

PonyBoy
12 days ago

Parents, read "Turtles All The Way Down" before you vaccinate your kids with any vaccines on the childhood schedule.
You'll be glad you did.

12 0 Reply • Share ›

drw22
12 days ago

Twelve babies died during the trial for this monoclonal vaxx, but the manufacturer doesn't have to prove the deaths weren't caused by their vaxx? They can just say they weren't? How many babies died in the control group? Since there's no mention, does that mean there wasn't a control group? They can get away with murdering infants and nobody bats an eye?

If 25 babies die a year from RSV, and half that died in the trial, then once they've vaxxed double the trial number, they'll likely hit the same number of deaths. I'd rather go with the Russian roulette of waiting to see if the baby gets sick. Seems like the odds of survival are better.

11 0 Reply • Share ›

Rob DF → drw22
12 days ago

Better? That's 25 babies a year for ALL the babies in the US versus 12 in a tiny clinical trial. Dark humor at it's finest.

3 0 Reply • Share ›

Shauna Link
12 days ago

12 died out of how many in the study. There would be no way in hell that I would give this to a kid of mine. CDC has proven to me how corrupt they are all in the name of $$$$$$...... nothing to do with health.

8 0 Reply • Share ›

Ron Roy → Shauna Link
11 days ago

Those were only the deaths. How many were severely physically and mentally injured.

1 0 Reply • Share ›

jprexena
12 days ago

Because these death jabs create more customers for big pharma that suits control and depopulation agenda. No surprise coming from the centers for disease creation. It's those who give their consent and power to these organizations and those who seek to rob and rule you better doesn't help in the slightest. Unfortunately, you have have the ignorant followers who will obey orders no matter how evil they are, including murder. As they will never question authorities nor will take the time to find out what's really in these jabs that so and so wants in your kids bodies that is so important. So much for common sense with discernment as these jabs and others are designed to cause mass harm and death. Since these jabs have murdered twelve kids in the trials, wouldn't that raise red flags for parents? Call for what it is cognitive dissonance, willful ignorance, and mass psychosis.
https://learntherisk.org/
https://operationdisclosure...
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7 0 Reply • Share ›

freedomandjusticeforall
12 days ago

Yup, just keep up on the 'depopulation', which Kamala Harris claims will help, '...your child breath easier.'

7 0 Reply • Share ›

Darby O'Gill
12 days ago edited

CDC okay with a few baby deaths ?? These same people are the most pro abortion people on the planet so why would a few casualties matter ? Sometimes I think they might want everyone over the age of 60 to take a long walk off a short pier. But,of course, I exaggerate. :o)

10 1 Reply • Share ›

kris
12 days ago

And if the parents who believed the big pharma lies and now lost their kids during the trial try to speak up or warn other parents... what will social media do to them? Try to censor them and accuse then of spreading misinformation and endangering public health. So tragic.

And if there was a control group.. you know they cooked the books by offering another vaccine with similar injuries.. NOT a saline injection.. like a real control group would have..

5 0 Reply • Share ›

donegoing2002
12 days ago

Remember Pharma has always lied to us. They're lying now. They'll always lie.

4 0 Reply • Share ›

George Washington
12 days ago

It's way past time to end the CDC. They are nothing but a criminal agent pushing the illicit drugs of big pharma. Decent people at the CDC should open their eyes and walk away from what is happening. Save your souls.

3 0 Reply • Share ›

Meave G.
12 days ago edited

This will probably kill a lot more babies per year than 25. But it will make Pharma a lot of money.

3 0 Reply • Share ›

YouKiddinMe
12 days ago

Just heard a radio commercial pushing the RSV vaccine. Idiot parents will be convinced their kid needs it. Same ol, same ol.

2 0 Reply • Share ›

Dean Jackson
12 days ago edited

"Despite 12 Deaths During Clinical Trials, CDC Signs Off on RSV Shots for Newborns"

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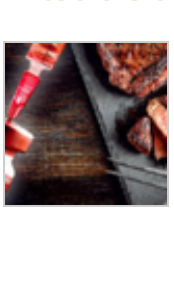

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Multiply that by 10 (CDC's VAERS website only captures 10% of deaths, and less than 1% of adverse events).

Thereby proving the Satanist co-option of our institutions (who use the more numerous Marxists to do their bidding), because, as I've already warned readers regarding the coronavirus, there are no vaccines for any cold virus, RSV and coronaviruses being cold viruses...

Cold viruses:

"What's Causing My Cold?

...

It's likely that someday you'll have a close encounter with one of these types:

Rhinovirus
Coronavirus

see more

2 0 Reply • Share ›

Meave G. Dean Jackson
12 days ago

The immune system is the best vaccine.

3 0 Reply • Share ›

Clare Goldsberry
11 days ago

A whole lot of new information, new studies, and research reports coming out about the dangers of infant vaccinations. I'm glad I had my children 50 years ago! This idea of killing infants -- through "vaccines" and "full term abortions" has gone beyond the pale! What have we become? A nation of eugenicists!

1 0 Reply • Share ›

S **Sima Jima**
11 days ago

Who offers their kids up to be tested?

CDC, we will test your kids... If it doesn't go right, your kid dies.

Huh... What...Who does that to their kids?

1 0 Reply • Share ›

J **Jennifo**
9 days ago edited

WTH. WHO in the hell places their baby on the alter in a trial study!!? I'm outraged that these stupid parents allowed it. Just enraged.

0 0 Reply • Share ›

Conservative Atheist
10 days ago

Whenever I read an article stating babies died during the trial, I question whether the parents were required to sign a form saying they weren't allowed to discuss the effects of the vaccines, because if my baby died after receiving any vaccine (my children were never vaccinated), especially during a trial, I would be screaming from the rooftops; "DO NOT GIVE YOUR CHILD THIS VACCINE!!!"

0 0 Reply • Share ›

BChristine
11 days ago

Just CRIMINAL.

0 0 Reply • Share ›

Leslie Benjamini
12 days ago

This is just one more criminal decision by the powers that be to put money over children's lives. These decisions will turn people into anti vaxxers.

0 0 Reply • Share ›

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